

Appln No.: 09/557,955
Amendment Dated: October 23, 2003
Reply to Office Action of March 27, 2003

REMARKS/ARGUMENTS

This is in response to the Office Action mailed March 27, 2003 for the above-captioned application. Reconsideration and further examination are respectfully requested.

This is a resubmission of an Amendment After Final on August 4, 2003. In an Advisory Action mailed October 3, 2003, the Examiner refused entry of the amendment stating that "the amendments to the claims now require specifically defined improvement that were unclear or undefined in the previous amendment and as such would require new search and consideration." Applicants respectfully submit that the refusal to enter the amendment is inappropriate in this case.

As a first matter, the amendment to claim 9 (the independent Jepson claim) is in direct response to a rejection for lack of definiteness of that appeared in the Office Action of March 27, 2003. The Examiner acknowledges that this non-entered amendment to claim 9 would overcome the rejection under 35 USC § 112, second paragraph from that office action. Thus, entry of this amendment will simplify issues on appeal since otherwise, the 112 issue will be taken up in the Appeal as well. The remaining amendments in the original amendment are also directly responsive to the § 112 second paragraph rejection, and should be effective to overcome this rejection. These amendments deal only with formalistic requirements, and nothing about these amendment changes the scope of the invention. Thus, the Examiner's unexplained assertion that additional search would be required is unclear.

It is noted that in the Advisory Action, the Examiner stated that "claims 10 and 11 remain confusing because Applicants appear to try to limit the preamble." Only claims 7 and 8, and not claims 10 and 11 were rejected on this ground in the Office Action of March 27. Thus, Applicants have amended claims 10 and 11 in this paper to respond to the Examiner's remark, and this amendment should also be entered.

No extension of time should be required as a Notice of Appeal has been filed. However, should one be required Applicants request an extension of time sufficient to make this paper timely and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

The Examiner also indicated that the art rejection was maintained because "in a product claim in Jepson format, method steps or intended use do not structurally distinguish the direct particulate label from the particulate label of the prior art." This statement is not understood, and is further addressed below.

Entry of this amendment and reconsideration of the application in view of the remarks

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herein are respectfully requested.

The Examiner has indicated that claims 12-20 are allowed.

Claims 2-11 stand rejected under 35 USC 112, second paragraph, as indefinite. Applicants respectfully traverse this rejection. The Examiner states that it is unclear whether the claim is directed to an assay device, a process of assaying, or the particulate reagent. Applicants do not understand that basis for this statement since claim 9 plainly begins with the phrase "In an assay device..." and all of the dependent claims refer to "an assay device."

The Examiner also states that the claim is confusing because "the prior claim required binding of the labeled reagent in a detection and control zone. Now the claim states that the non-specific protein which can participate." Applicants submit that the claim stands on its own, and should not be judged based on a prior claim. More importantly, however, the claim is directed to an assay device as it would be provided for use in testing. At this time, the labelled reagent has not yet been carried into the detection and control zones (an event which occurs when the device is used) and therefore the control reaction has not occurred, it is a reaction that **can occur** because of the binding specificity. To clarify this point, Applicants have amended claim 9.

The Examiner's statement that claim 9 does not comply with 37 CFR § 1.75(e) is also not understood. The claim clearly includes a preamble portions, a reference to an improvement, and a section of elements, steps and/or relationships that are set forth as the new or improved portion.

The Examiner's statements concerning claims 5-7 appears to be based on the application of a standard to Jepson claims that is different from other claim formats, including a requirement that the portion of a dependent claim which is admitted prior art must be clearly delineated. Applicants are not aware of any reason why the dependent claims in this application are required to meet any standard other than that of allowing a person skilled in the art to understand the scope of the claim, when read in light of the specification. Furthermore, Applicants do not agree with the Examiner's implied suggestion that the level of skill in the art is so low as to preclude understanding of the claims as they are now presented. Nevertheless, to facilitate allowance amendments in line with the Examiner's comments have been made.

With respect to claim 8, the Examiner asserts that antecedent basis is still lacking, but does not say why. Claim 8 read "An assay device according to claim 7, wherein said ratio is about 3:1." Claim 7 refers to a ratio, which is at least 2:1. No ambiguity is seen in these claims. One simply takes claim 7 and replaces the words "at least 2:1" with "about 3:1" to arrive at claim 8.

On the merits, the Examiner has applied US Patent No. 5,662,871 of May as

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anticipating the claims 5, 9, 10 and 11. Claim 9 has been amended to make it clear that the labeled reagent is captured in the control zone as a result of binding of the non-specific protein. The BSA in May serves solely as a blocking agent, and is not involved in any binding reaction. Thus, claim 9, as amended, as well as claims 5, 10 and 11 which are dependent thereon are not anticipated by May.

The Examiner in the Advisory Action indicated that the art rejection was maintained because "in a product claim in Jepson format, method steps or intended use do not structurally distinguish the direct particulate label from the particulate label of the prior art." Applicants do not understand this statement. The argument is that BSA, the non-specific protein in May is used to block binding sites on the substrate. It is not part of the particulate direct label, but part of the substrate. This is a structural difference (i.e., it is in a different location within the device), not merely a statement of method or intended use. This structural difference is reflected in the fact that the BSA in bind does not bind to anything during the use of the device, and therefore is different from the non-specific protein of the invention which does "participate in a control reaction with another specific binding agent ... to capture the labelled reagent in the control zone." Thus, the rejection over May should be withdrawn.

As previously noted in the unentered amendment, additional differences which exist between claims 5, 10 and 11 and the cited art. May does not disclose a second population of direct particulate labels cosensitized only with the non-specific protein as in claim 5, and the Examiner has not indicated how this limitation is met by the reference. The Examiner also has not indicated how May discloses a control zone with a specific binding agent which binds to the non-specific protein as required in claims 10 and 11. Applicants submit that if the rejection is not withdrawn, these issues should be addressed to facilitate complete understanding of the issues for appeal.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,



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OCT 23 2003